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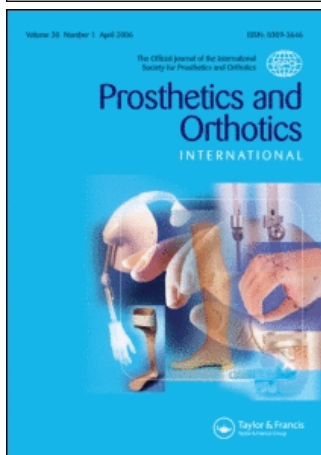
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Prosthetic prescription in the Netherlands: an observational study

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Abstract

Prosthetic prescription for lower limb amputees and the methodology used are primarily based on empirical knowledge. Clinical expertise plays an important role that can lead to an adequate prescription; however, a clear evidence based motivation for the choices made cannot be given. This can lead to local prescription variations with regard to overuse or underuse of prosthetic care and a lack of transparency for consumers and health insurance companies. Hence a clinical guideline may lead to a more consistent and efficient clinical practice and thus more uniformly high quality care.

The purpose of this study was to get insight into potential similarities in prescription criteria in clinical practice in the Netherlands. Secondly, the authors were interested to know if prosthetic prescription was primarily based on the level of activity or intended use of the prosthesis.

As part of the development of a consensus-based clinical guideline a multi-centred, cross-sectional study was carried out in order to observe the prosthetic prescription for a group of lower limb amputees. Therefore prescription data were collected from 151 amputees with trans-femoral amputation, knee disarticulation or trans-tibial amputation.

Results of the multiple logistic regression show no relationship between the activity level and any of the variables included in the equation such as the hospital or medical doctor in

Physical and Rehabilitation Medicine (MD in P&RM), prosthetic components, age of the amputee or reason of amputation. The criteria used are merely based on the clinical expertise and local experience whereas the actual prescriptions differ from location to location.

In conclusion the development of a clinical guideline for prosthetic prescription in lower limb amputation is recommended. The information gained from this observational study will be used in a clinical guideline procedure for prosthetic prescription in the Netherlands.

Introduction

In the Netherlands the incidence of major lower limb amputation is about 19 per 100,000 habitants (CBS, 1999). These include amputations from the trans-metatarsal to the trans-pelvic level. For an amputee population in the north of the Netherlands in 1991 and 1992 (Rommers *et al.*, 1996) approximately 82% of the total lower limb amputations occurred as a result of vascular diseases, 9% were traumatic amputations and 9% were the result of oncological conditions. Stewart and Jain (1993) found similar figures in Scotland. In the Netherlands, 86% of all lower limb amputations are trans-femoral (TF) (34%), knee disarticulation (KD) (10%) or trans-tibial (TT) (42%) (CBS, 1999). Of these amputees, 48% were fitted with a prosthesis (Rommers *et al.*, 1997).

In the Netherlands a prosthesis is prescribed in clinical practice by a medical doctor in Physical and Rehabilitation Medicine (MD in P&RM) in collaboration with a prosthetist and sometimes with the advice of a physical therapist. This clinical practice is mostly located in

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rehabilitation centres or general hospitals. The role of the MD in P&RM and the prosthetist as members of a clinical team is slightly different from that in other industrialised countries. The MD in P&RM is not only responsible for information on medical aspects but also has a leading role in choosing the prosthetic components. In addition, the training level of the prosthetists has been of a lower category up to now.

In the Netherlands, and probably everywhere else in the world, prosthetic prescription for lower limb amputees and the used methodology are primarily based on empirical knowledge. This knowledge is transmitted to professionals by "residents' clinical training" and is further developed and renewed in clinical practice and by courses and symposia. These developments and renewals have not been established in a standardised way, i.e. there is no existing clinical guideline. Experience plays an important role that can lead to an adequate prescription; however, a clear evidence-based motivation for the choices made cannot always be given. This can lead to local prescription variations as to overuse or underuse of prosthetic care and a lack of transparency for consumers and health insurance companies. Hence a clinical guideline can lead to a more consistent and efficient clinical practice and more uniformly high quality care (Trickey *et al.*, 1998; Woolf *et al.*, 1999).

Multiple factors must be considered in the prosthetic prescription for an individual amputee. The amputee's general health (comorbidity), mental state, living circumstances and vocational interests must be considered in addition to the level of amputation (Bowker, 1992; Rubin *et al.*, 1996). There is a growing awareness that the prescription has to match the intended use of a prosthesis (Menard *et al.*, 1992; Cortes *et al.*, 1997).

Classification of amputees based on functional abilities can be of use in differentiating among the different levels of prosthetic prescription (Gailey *et al.*, 2002). In general terms a prosthetic prescription should be based on matching the functional needs of the amputee with the functional capacities of the prosthetic device (Cortes *et al.*, 1997). In the authors' view an adequate instrument in the classification of amputees for prosthetic prescription is not available. The Special Interest Group for Amputee Medicine (SIGAM) of the British Society of

Rehabilitation Medicine (BSRM) uses a validated scale of "disability mobility grades" in prosthetic prescription (Stewart, 2001). Several questionnaires on prosthetic use, functional aspects of a prosthesis and general activities are available too. However, none of these offer explicit information on how to translate the amputee's functional ability into an adequate prosthetic prescription (Alaranta *et al.*, 1994; Gauthier-Gagnon *et al.*, 1998; MacFarlane *et al.*, 1997). A mobility scale can be a good starting point. However, Rommers *et al.* (2001) found that the existing mobility instruments for lower limb amputees differ considerably and only measure certain aspects of mobility. In the authors' opinion for this study the 5-level functional classification used by the US Health Care Financing Administration (HCFA) is most suitable (HCFA, 2001). Based on this classification Gailey *et al.* (2002) developed "The Amputee Mobility Predictor" as a valid instrument to measure the ability to ambulate with a prosthesis. However, prosthetic prescription needs additional research.

There are some difficulties in using the results from studies on biomechanical aspects and functional characteristics of several prosthetic components for prescription criteria. Outcome measures differ from study to study, therefore comparison or meta-analysis of the results is difficult. However, the explicit knowledge derived from literature is needed to develop a clinical guideline (Woolf *et al.*, 1999). In cases where literature findings are not appropriate or subject areas have not been researched, development of a clinical guideline has to rely on other sources of evidence. Accordingly, professionals can provide expert opinion and in addition knowledge from clinical experience (Rycroft-Malone, 2001).

As part of the development of a consensus-based clinical guideline the authors gathered implicit information on prosthetic prescription in the Netherlands by using an observational study of prescription in clinical practice and an interview with leading experts in the field of prosthetics.

The purpose of this study was to get insight into possible similarities in prescription criteria in practice. Secondly, it was of interest to discover if prosthetic prescription was primarily based on the amputee's level of activity or the intended use of the prosthesis.

The results will be used in the guideline-developing consensus procedure carried out in the Netherlands concerning the prescription for prostheses of the lower limb.

Methodology

Subjects

In the present study a multi-centred, cross-sectional study was carried out in order to observe the prosthetic prescription of a group of lower limb amputees. To collect these data, 16 hospitals were selected. A hospital was included if sufficient and adequate expertise on amputation and prosthetics was present in the rehabilitation team that provided the prosthesis. The MD in P&RM within those teams were all members of a professional working-group of physicians in P&RM focused on amputation and prosthetics in the Netherlands. Secondly the amount of prosthetic prescriptions in the selected hospitals had to exceed 100 prescriptions on an annual basis. The selected hospitals were evenly distributed across the Netherlands.

Data were collected from inpatient and outpatient amputees with a TF amputation, KD or TT amputation. Patients with primary as well as secondary amputations were included. There were no restrictions concerning age, gender or race of the amputees, on the side and date of the amputation or the reason for amputation.

Since no valid assessment instrument was available, an assessment form was developed on which data of patient, hospital and prosthesis could be recorded in a standardised way.

For classification of the amputee's level of activity the coding system of the HCFA seemed the most appropriate (HCFA, 2001):

- if an amputee has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence, he or she is assessed as K1. This can be typified as a limited and unlimited household ambulator;
- a K2-amputee has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as kerbs, stairs or uneven surfaces. This is typical for the limited community ambulator;
- a more active amputee with the ability or potential for ambulation with variable cadence is assessed as K3. This is a community ambulator who has the ability to traverse most obstacles and may have

vocational, therapeutic or exercise activities that demand prosthetic utilisation beyond simple locomotion;

- most active amputees are graded as K4 and have the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. This is typical for the prosthetic demands of a child, an active adult or an athlete.

The observations were performed by two researchers (HL and CH). The observed decisions or remarks were extended with questions to rehabilitation-team members or amputees when items on the structured observation list were not mentioned. The activity level resulted from the appraisal of both the remarks of the team members and the amputees on this subject.

Analysis

To facilitate the analyses, level of activity was assessed as a dichotomous variable. Therefore the amputees were classified into two levels of activity. Activity level 1 included K1 and K2-amputees, whereas activity level 2 included the K3 and K4-amputees.

The Netherlands was divided into three areas: the northern and eastern parts including 7 hospitals, the western part with 6 hospitals, and the southern area with 3 hospitals. Other variables were age, sex, level of amputation, reason for amputation, date of amputation, primary or secondary prosthesis and comorbidity. Codes of these variables are given in Figure 1. Prosthetic prescription variables were coded in the categories: socket, weight-bearing and suspension principle, knee- and ankle-foot mechanism.

Data were processed using SPSS version 9.0 and Egret. The statistical procedures used were Spearman correlations and Multiple Logistic Regressions. The logistic regression analysis was performed on the binary variable activity level to find relationships between activity level and prosthetic prescription, patient data and data of the hospitals visited.

Results

The studied population consisted of 151 amputees, including 3 bilateral ones, of whom both prostheses were separately recorded in the databases. The realisation of 154 prosthetic

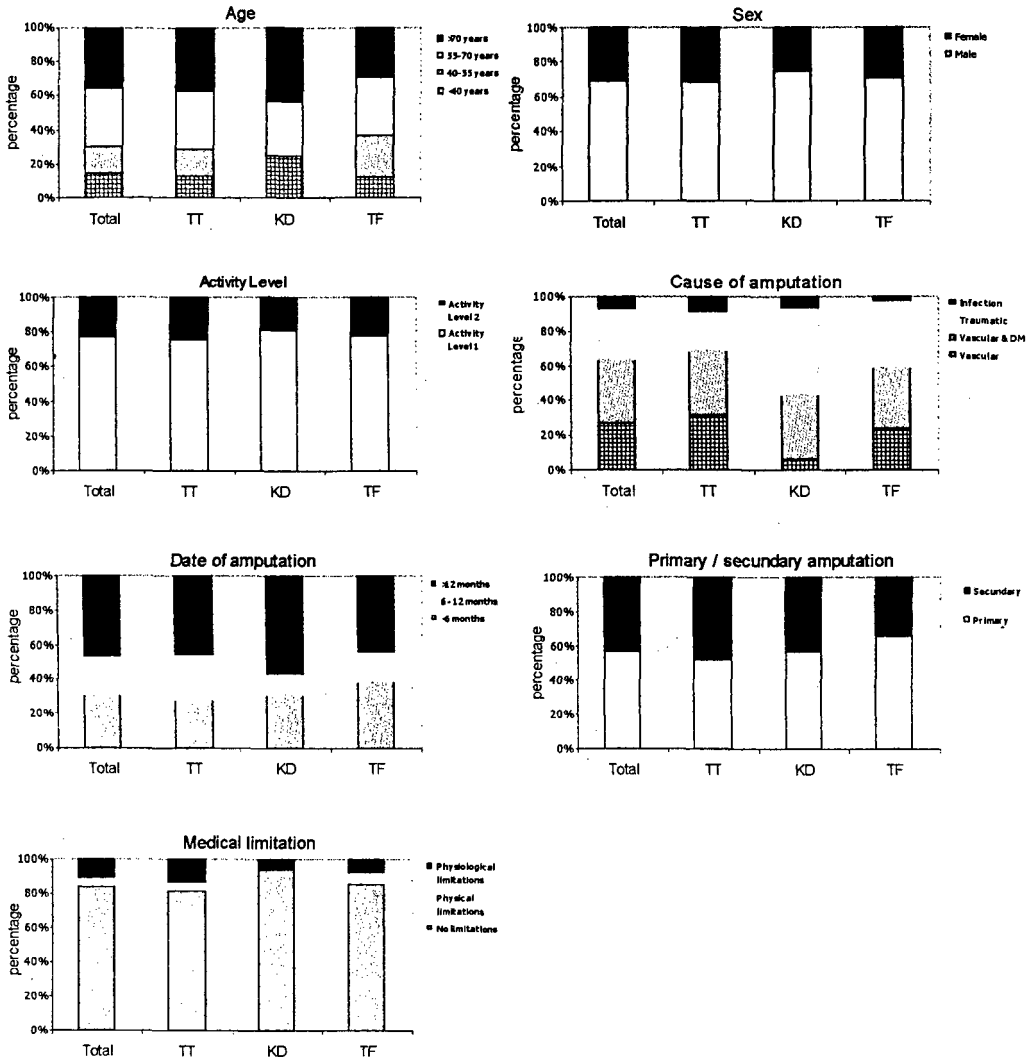


Fig. 1. Amputees' demographics: 'Total' = total database (n=151), 'TT' = database trans-tibial amputees (n=94), 'KD' = database knee disarticulation amputees (n=16), 'TF' = database trans-femoral amputees (n=41).

prescriptions for major lower limb amputations was observed during 25 visits to 16 hospitals in the Netherlands. For 1 amputee the assessment form was incomplete and therefore it was left out of the databases. For 2 amputees it was impossible to assess their activity level, because these patients were amputated for complex regional pain syndrome type I (CRPS I) and the patient as well as the MD in P&RM were uncertain about the future activities of the amputee. These 3 amputees were left out of the database, in all, the total database included 151 prescriptions of whom 94 cases were TT

amputees (62%), 41 TF cases (27%) and only 16 cases (11%) were KD amputees.

The majority of the studied population was 70 years or older (37%), the group of 55-70 year olds was somewhat smaller (35%) (Fig. 1). Seventy per cent (70%) was male and 75% of the studied population was graded into the group with activity level 1. In 36% of the cases amputation was performed because of vascular reasons (with or without diabetes mellitus), in 27% and 29% respectively amputation had been performed for vascular or traumatic/ oncological/congenital reasons, respectively.

Table 1a: Prosthetic components for trans-tibial prostheses (94 prescriptions).

Suspension			Weight bearing			Prosthetic feet		
	Act. 1	Act. 2		Act. 1	Act. 2		Act. 1	Act. 2
Supracondylar	28 (39)	6 (26)	PTB	67 (94)	21 (92)	Solid Ankle	35 (49)	4 (18)
Liner	22 (31)	12 (52)	Femur	4 (6)	1 (4)	Single Axis	9 (13)	5 (22)
Femur	2 (3)	2 (9)	Combination	0 (0)	1 (4)	Energy Storing	6 (8)	7 (30)
Combination	19 (27)	3 (13)				Multi Flexible	21 (30)	7 (30)
Total	71 (100)	23 (100)	Total	71 (100)	23 (100)	Total	71 (100)	23 (100)

Table 1b: Prosthetic components for knee disarticulation prostheses (16 prescriptions).

Suspension			Weight bearing			Prosthetic feet		
	Act. 1	Act. 2		Act. 1	Act. 2		Act. 1	Act. 2
Supracondylar	7 (54)	0 (0)	Condylar	13 (100)	3 (100)	Solid Ankle	7 (54)	1 (33)
Liner	5 (38)	3 (100)				Single Axis	3 (23)	2 (67)
Combination	1 (8)	0 (0)				Energy Storing	1 (8)	0 (0)
						Multi Flexible	2 (15)	0 (0)
Total	13 (100)	3 (100)	Total	13 (100)	3 (100)	Total	13 (100)	3 (100)
Socket			Prosthetic knee			Knee-lock		
	Act. 1	Act. 2		Act. 1	Act. 2		Act. 1	Act. 2
Open socket	5 (38)	1 (33)	Single axis	1 (8)	0 (0)	Without knee lock	13 (100)	3 (100)
Closed socket	8 (62)	2 (67)	4 axes	7 (54)	2 (67)	Knee lock	0 (0)	0 (0)
			>4 axes	5 (38)	1 (33)			
Total	13 (100)	3 (100)	Total	13 (100)	3 (100)	Total	13 (100)	3 (100)

Table 1c: Prosthetic components for trans-femoral prostheses (41 prescriptions).

Suspension			Weight bearing			Prosthetic feet		
	Act. 1	Act. 2		Act. 1	Act. 2		Act. 1	Act. 2
Vacuum	15 (47)	7 (78)	Tuber	12 (38)	4 (44)	Solid Ankle	13 (41)	3 (33)
Liner	7 (22)	0 (0)	NML	9 (28)	5 (56)	Single Axis	8 (25)	1 (11)
Pelvis	7 (22)	1 (11)	Combination	11 (34)	0 (0)	Energy Storing	3 (9)	0 (0)
Combination	3 (9)	1 (11)				Multi Flexible	8 (25)	5 (56)
Total	32 (100)	9 (100)	Total	32 (100)	9 (100)	Total	32 (100)	9 (100)
Socket			Prosthetic knee			Knee lock		
	Act. 1	Act. 2		Act. 1	Act. 2		Act. 1	Act. 2
Quad	20 (63)	6 (67)	Single Axis	15 (47)	1 (11)	Without knee lock	22 (69)	9 (100)
Trilateral	1 (3)	0 (0)	4 Axes	13 (41)	5 (56)	Knee lock	10 (31)	0 (0)
NML	2 (6)	3 (33)	5 Axes	0 (0)	1 (11)			
Combination	9 (28)	0 (0)	7 Axes	4 (12)	2 (22)			
Total	32 (100)	9 (100)	Total	32 (100)	9 (100)	Total	32 (100)	9 (100)

Table 1d: Prosthetic feet for the total population (151 prescriptions).

Prosthetic feet		
	Act. 1	Act. 2
Solid Ankle	55 (47)	8 (23)
Single Axis	20 (17)	8 (23)
Energy Storing	10 (9)	7 (20)
Multi Flexible	31 (27)	12 (34)
Total	116 (100)	35 (100)

Act 1: amputees with activity level (K1 or K2). Act 2: amputees with activity level 2 (K3 or K4). In the tables the absolute figures (and percentages) are listed.

Most amputations had been performed more than 2 years before this study. In 57% of the total cases it concerned primary amputations. One hundred and twenty-seven (127) cases (84%) were free from medical limitations/restrictions, while 16 cases (11%) had physical restrictions such as cardiac diseases and 8 cases (5%) suffered from limitations due to rheumatoid arthritis or stroke.

Seventy-eight (78) (51%) of the amputees received their prostheses in the western part of the Netherlands, while 31% went to hospitals in the northern and eastern part of the country. Fifty percent (50%) of the MDs in P&MR were trained in the north and east of the Netherlands, 48% in the western part. The professional experience of the MDs in P&MR in the field of amputation and prosthetics did not seem to influence the prosthetic prescriptions.

The results of the observations on the prosthetic prescription for all 151 cases are shown in Table 1. Prosthetic prescription is split up for the three amputation levels and the activity level. Four different ankle-foot mechanisms were distinguished (solid-ankle, single-axis, energy-storing, multi-flexible). The solid-ankle foot is prescribed primarily for TT amputees with a lower activity level (49%). The energy-strong feet are prescribed more often in the prescriptions for TT amputees with a higher activity level (30% vs. 8%). However, the 4 identified ankle-foot mechanisms are evenly distributed for this activity level. For KD and TF amputees the choice for the prosthetic foot is not clearly related to the level of activity either.

Two aspects of the prosthetic socket were distinguished: the suspension and weight bearing principles. The authors noticed a distribution over the various principles for the 3 amputation levels, without a clear relationship to the level of activity. Single-axis or four-axes knee-mechanisms are prescribed merely for lower-activity TF amputees with a 31% knee lock in this group.

Results of the multiple logistic regression only showed a relation between the age of the amputee and the level of activity ($p < 0.001$, SE 0.27, coefficient -1.18). There were no relations between the activity level and any of the variables included in the equation, such as the hospital or MD in P&RM, prosthetic components, sex, co-morbidity or reason for amputation.

Discussion

The aim of this part of the study was to get insight into the degree of agreement on prosthetic prescription criteria for lower limb amputees in the Netherlands. The statistical results of the observation of clinical practice do not reveal any consensus between clinicians on criteria for prosthetic prescription. As to the second question of this study, there was no clear relationship between the level of activity and the prosthetic components within the prescriptions noted during the observational study. The criteria used are merely based on clinical expertise and local experience whereas the actual prescriptions differ from location to location. These prescription variations can either lead to underuse or overuse of prosthetic care in individual cases.

For none of the prosthetic components (prosthetic foot, knee mechanism and socket) was a relationship found with the level of activity, age of the amputee or time since amputation. Analysis of location in the Netherlands or years of experience of the MD in P&RM did not show any relationship with the prosthetic prescription. The total population size in this study was significant for an analysis on correlations. However, subgroups based on the level of amputation were too small to allow this analysis. Causes of amputation differed from those in the Dutch population as the authors only observed amputees who were thought to be able to function with a prosthesis.

During the observation of clinical practice the functional abilities of individual patients were mentioned in all individual cases ($n=151$); however, they were not explicitly translated into prosthetic prescription. The decisions seem to be more influenced by the local experience with prosthetic components and also based on the implementation of new products. But there was some agreement with regard to the prescriptions for the 3 different amputation levels. In TT-amputees the total of prescriptions of a gel-liner for amputees with a lower activity level was almost equal to that of the supracondylar-polyform fitting; whereas for the higher activity level the amount of prescriptions tended towards the gel-liner (66% vs. 34%). In literature the authors could not find any evidence for this subject. As for the prosthetic foot in TT amputees, a solid-ankle and a single-axis foot were prescribed in 62%

of the lower activity amputees and a multi-flexible foot in 30% of the subjects. For the higher activity level this was 39% and 30%, respectively. Hence no explicit agreement has been found in choosing the prosthetic foot in TT amputees related to the level of activity. Gait-analysis studies on this matter offer additional information. The solid-ankle foot is described as appropriate for lower-activity-level amputees, the single-axis foot for average-activity level and the multiple-axis foot for moderate-level amputees (Huang *et al.*, 2000). The energy-storing feet are more appropriate for active walking amputees (Casillas *et al.*, 1995; Menard *et al.*, 1992).

The motivation for the choice of the prosthetic foot in KD and TF amputees was widespread. Several arguments were given, for example its dependence on the choice of a specific prosthetic knee. The properties of a prosthetic knee during gait also depend on the properties of the prosthetic foot used. Other arguments were stability aspects during gait, level of activity of the amputee and the experience with various prosthetic feet. However, no clear agreement was found. Literature evidence on this subject is limited. A more symmetrical gait pattern was seen in TF amputees with a Flex-foot compared to those using a conventional foot (MacFarlane *et al.*, 1997).

For the prosthetic socket in KD amputation there is agreement on the use of a hard socket in combination with a polyform inner socket as a first choice and the use of a gel-liner in case of specific stump problems. There were, however, no prescriptions of gel-liners observed for KD amputees. In TF amputees the use of gel-liner sockets seems a new alternative. In the prescriptions 22% of the TF sockets contained a gel-liner, not however for a specific reason like stump problems or improvement of suspension.

There was a wide range of prosthetic knee-mechanisms used in the prescriptions, without a clear overall agreement. Arguments given for making a choice are most often a measure of control on knee stability and the intended walking speed.

From the observational study it can be concluded that there is some agreement on several items. Level of activity is an important factor when prescribing a prosthesis in lower limb amputees. However, no explicit criteria are at the prescribers' disposal when matching the functional ability of the prosthetic user with the

functional properties of prosthetic components or the complete prosthesis.

There was a wide range of prosthetic components used for TF, KD and TT amputees in this study. This could be expected due to a lack of guidelines for prescription criteria. Several authors state that the most important indicator for making choices in the prescription process is the functional ability of the amputee (Gailey *et al.*, 2002; Goh *et al.*, 1984; Menard *et al.*, 1992; Postema *et al.*, 1997). In the authors' opinion the use of a classification based on these functional abilities is therefore to be recommended. In addition, it seems appropriate to look at aspects of activities of daily life, such as employment-related factors, to complete the intended use.

Another cause of the lack of consensus and the wide range of prosthetic components used can be found in the level of training and the experience of the prosthetic team members. The introduction of a university course for prosthetists could offer more consistent information for the clinical team on functional aspects of prosthetic components. Therefore, the prosthetist ought to have a more important role in the prescription process than has been the case up to now. Recently the upgrading of the prosthetist's educational level has started in the Netherlands. Secondly, the continuing education of MD in P&RM is necessary in order to assure consistency in knowledge about possible medical problems and functional abilities of amputees.

It is concluded that there is no consensus in the Netherlands on prescription criteria for prosthetic components in lower limb amputation. However, the agreements found in this study offer the opportunity for further development of a consensus-based clinical guideline on prosthetic prescription. The development of clinical guidelines is a way of making prosthetic care more consistent and efficient and of diminishing the gap between what clinicians do and what scientific evidence supports (Woolf *et al.*, 1999). Guidelines for prosthetic prescription can be of use now there are more and more options for prosthetic components. In the Netherlands third party payers increasingly ask for more extended motivation for costly prostheses. For the consumer more transparency is necessary too, when quality of care becomes more important.

Recommendations

The development of a clinical guideline for prosthetic prescription in the Netherlands in lower limb amputation is recommended. The use of a classification of amputees based on mobility can be a starting point when defining intended use with an additional status of activities in daily life and participation such as vocational interests. The information gained from this observational study will be combined with the implicit knowledge given by professional experts and the scientific evidence from the available literature. This combined knowledge will be used in a clinical guideline procedure for prosthetic prescription in the Netherlands.

Last but not least consumers should take part in such a process. Lower limb amputee patients can also take part in developing clinical guidelines to provide "expert patient opinions" on care options (Rycroft-Malone, 2001). Therefore a consumer questionnaire is recommended as part of a consensus procedure on prosthetic prescription.

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